## **Introduced by Assembly Member Plescia**

February 22, 2006

An act to amend Section 2472 of, and to repeal Section 4190 of, the Business and Professions Code, and to amend Sections 1201, 1204, 1206, 1214.1, 1242, and 1248.1 of, to add Sections 1200.2 and 1204.2 to, and to repeal Section 1233 of, the Health and Safety Code, relating to health clinics.

## LEGISLATIVE COUNSEL'S DIGEST

AB 2308, as introduced, Plescia. Ambulatory surgical centers: licensure.

Existing law provides for the licensure and regulation of health facilities and clinics, including specialty clinics, by the State Department of Health Services. Existing law defines a specialty clinic to include a surgical clinic that is not part of a hospital and that provides ambulatory surgical care for patients who remain less than 24 hours. A violation of these provisions is a crime.

This bill would repeal the definition of a surgical clinic for purposes of various licensure and regulatory requirements, would make various conforming changes, and would require the licensure of ambulatory surgical centers, as specified. The bill would require a licensed ambulatory surgical center to meet specified requirements. By creating new crimes, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

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This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

*The people of the State of California do enact as follows:* 

- SECTION 1. Section 2472 of the Business and Professions Code is amended to read:
  - 2472. (a) The certificate to practice podiatric medicine authorizes the holder to practice podiatric medicine.
  - (b) As used in this chapter, "podiatric medicine" means the diagnosis, medical, surgical, mechanical, manipulative, and electrical treatment of the human foot, including the ankle and tendons that insert into the foot and the nonsurgical treatment of the muscles and tendons of the leg governing the functions of the foot.
  - (c) A doctor of podiatric medicine may not administer an anesthetic other than local. If an anesthetic other than local is required for any procedure, the anesthetic shall be administered by another licensed health care practitioner who is authorized to administer the required anesthetic within the scope of his or her practice.
  - (d) (1) A doctor of podiatric medicine who is ankle certified by the board on and after January 1, 1984, may do the following:
  - (A) Perform surgical treatment of the ankle and tendons at the level of the ankle pursuant to subdivision (e).
  - (B) Perform services under the direct supervision of a physician and surgeon, as an assistant at surgery, in surgical procedures that are otherwise beyond the scope of practice of a doctor of podiatric medicine.
  - (C) Perform a partial amputation of the foot no further proximal than the Chopart's joint.
  - (2) Nothing in this subdivision shall be construed to permit a doctor of podiatric medicine to function as a primary surgeon for any procedure beyond his or her scope of practice.
- 30 (e) A doctor of podiatric medicine may perform surgical 31 treatment of the ankle and tendons at the level of the ankle only 32 in the following locations:

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- (1) A licensed general acute care hospital, as defined in Section 1250 of the Health and Safety Code.
- (2) A licensed surgical clinic, as defined in Section 1204 of the Health and Safety Code, if the doctor of podiatric medicine has surgical privileges, including the privilege to perform surgery on the ankle, in a general acute care hospital described in paragraph (1) and meets all the protocols of the surgical clinic.
- (3)—An ambulatory surgical center that is certified to participate in the Medicare Program under Title XVIII (42 U.S.C. Sec. 1395 et seq.) of the federal Social Security Act, if the doctor of podiatric medicine has surgical privileges, including the privilege to perform surgery on the ankle, in a general acute care hospital described in paragraph (1) and meets all the protocols of the surgical center.

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(3) A freestanding physical plant housing outpatient services of a licensed general acute care hospital, as defined in Section 1250 of the Health and Safety Code, if the doctor of podiatric medicine has surgical privileges, including the privilege to perform surgery on the ankle, in a general acute care hospital described in paragraph (1). For purposes of this section, a "freestanding physical plant" means any building that is not physically attached to a building where inpatient services are provided.

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- (4) An outpatient setting accredited pursuant to subdivision (g) of Section 1248.1 of the Health and Safety Code.
- (f) A doctor of podiatric medicine shall not perform an admitting history and physical examination of a patient in an acute care hospital where doing so would violate the regulations governing the Medicare program.
- (g) A doctor of podiatric medicine licensed under this chapter is a licentiate for purposes of paragraph (2) of subdivision (a) of Section 805, and thus is a health care practitioner subject to the provisions of Section 2290.5 pursuant to subdivision (b) of that section.
- 37 SEC. 2. Section 4190 of the Business and Professions Code is repealed.
  - 4190. (a) Notwithstanding any provision of this chapter, a surgical clinic, as defined in paragraph (1) of subdivision (b) of

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Section 1204 of the Health and Safety Code may purchase drugs at wholesale for administration or dispensing, under the direction of a physician, to patients registered for care at the clinic, as provided in subdivision (b). The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of seven years for inspection by all properly authorized personnel.

- (b) The drug distribution service of a surgical clinic shall be limited to the use of drugs for administration to the patients of the surgical clinic and to the dispensing of drugs for the control of pain and nausea for patients of the clinic. Drugs shall not be dispensed in an amount greater than that required to meet the patient's needs for 72 hours. Drugs for administration shall be those drugs directly applied, whether by injection, inhalation, ingestion, or any other means, to the body of a patient for his or her immediate needs.
- (e) No surgical clinic shall operate without a license issued by the board nor shall it be entitled to the benefits of this section until it has obtained a license from the board. Each license shall be issued to a specific clinic and for a specific location.
- SEC. 3. Section 1200.2 is added to the Health and Safety Code, to read:
- 1200.2. (a) As used in this chapter, "clinic" also means an ambulatory surgical center that is not part of a hospital and which, pursuant to Section 1204.2, primarily provides surgical services that do not exceed an average of four hours of total operating time to patients who do not require overnight hospitalization or who do not pose a significant safety risk according to classifications determined by the American Society of Anesthesiologists and, beginning at a time of postoperative care, remain less than 24 hours.
- (b) An ambulatory surgical center does not include any place or establishment owned or leased and operated as a clinic or office by one or more physicians and surgeons, podiatrists, or dentists in individual or group practice, regardless of the name used publicly to identify the place or establishment, provided, however, that physicians and surgeons, podiatrists, or dentists may, at their option, apply for licensure.

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SEC. 4. Section 1201 of the Health and Safety Code is amended to read:

1201. "License" means a basic permit to operate a clinic. A license may only be granted to a clinic of a type enumerated in Section 1204-or, 1204.1, or 1204.2, and the license shall not be transferable. However, the issuance of a license upon a change of ownership shall not of itself constitute a project within the meaning of Section 127170.

- SEC. 5. Section 1204 of the Health and Safety Code is amended to read:
- 1204. Clinics eligible for licensure pursuant to this chapter are primary care clinics—and, specialty clinics, and ambulatory surgical centers.
- (a) (1) Only the following defined classes of primary care clinics shall be eligible for licensure:
- (A) A "community clinic" means a clinic operated by a tax-exempt nonprofit corporation that is supported and maintained in whole or in part by donations, bequests, gifts, grants, government funds or contributions, that may be in the form of money, goods, or services. In a community clinic, any charges to the patient shall be based on the patient's ability to pay, utilizing a sliding fee scale. No corporation other than a nonprofit corporation, exempt from federal income taxation under paragraph (3) of subsection (c) of Section 501 of the Internal Revenue Code of 1954 as amended, or a statutory successor thereof, shall operate a community clinic; provided, that the licensee of any community clinic so licensed on the effective date of this section shall not be required to obtain tax-exempt status under either federal or state law in order to be eligible for, or as a condition of, renewal of its license. No natural person or persons shall operate a community clinic.
- (B) A "free clinic" means a clinic operated by a tax-exempt, nonprofit corporation supported in whole or in part by voluntary donations, bequests, gifts, grants, government funds or contributions, that may be in the form of money, goods, or services. In a free clinic there shall be no charges directly to the patient for services rendered or for drugs, medicines, appliances, or apparatuses furnished. No corporation other than a nonprofit corporation exempt from federal income taxation under paragraph (3) of subsection (c) of Section 501 of the Internal

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Revenue Code of 1954 as amended, or a statutory successor thereof, shall operate a free clinic; provided, that the licensee of any free clinic so licensed on the effective date of this section shall not be required to obtain tax-exempt status under either federal or state law in order to be eligible for, or as a condition of, renewal of its license. No natural person or persons shall operate a free clinic.

- (2) Nothing in this subdivision shall prohibit a community clinic or a free clinic from providing services to patients whose services are reimbursed by third-party payers, or from entering into managed care contracts for services provided to private or public health plan subscribers, as long as the clinic meets the requirements identified in subparagraphs (A) and (B). For purposes of this subdivision, any payments made to a community clinic by a third-party payer, including, but not limited to, a health care service plan, shall not constitute a charge to the patient. This paragraph is a clarification of existing law.
- (b) The following types of specialty clinics shall be eligible for licensure as specialty clinics pursuant to this chapter:
- (1) A "surgical clinic" means a clinic that is not part of a hospital and that provides ambulatory surgical care for patients who remain less than 24 hours. A surgical clinic does not include any place or establishment owned or leased and operated as a clinic or office by one or more physicians or dentists in individual or group practice, regardless of the name used publicly to identify the place or establishment, provided, however, that physicians or dentists may, at their option, apply for licensure.

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 (1) A "chronic dialysis clinic" means a clinic that provides less than 24-hour care for the treatment of patients with end-stage renal disease, including renal dialysis services.

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(2) A "rehabilitation clinic" means a clinic that, in addition to providing medical services directly, also provides physical rehabilitation services for patients who remain less than 24 hours. Rehabilitation clinics shall provide at least two of the following rehabilitation services: physical therapy, occupational therapy, social, speech pathology, and audiology services. A rehabilitation clinic does not include the offices of a private physician in individual or group practice.

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(3) An "alternative birth center" means a clinic that is not part of a hospital and that provides comprehensive perinatal services and delivery care to pregnant women who remain less than 24 hours at the facility.

- SEC. 6. Section 1204.2 is added to the Health and Safety Code, to read:
- 1204.2. (a) Notwithstanding Section 1248, in addition to the primary care clinics and specialty clinics specified in Section 1204, clinics eligible for licensure pursuant to this chapter include ambulatory surgical centers. Nothing in this chapter shall prohibit an ambulatory surgical center from referring a nonemergency patient to a lower classification facility.
- (b) Failure to comply with this section may be grounds for denial, revocation, or suspension of the license by the department.
- (c) The department may accept accreditation by an accreditation agency, as defined in subdivision (d) of Section 1248, as evidence that an ambulatory surgical center demonstrates compliance with, or meets the initial licensing requirements set forth in, this chapter.
- (d) The department may contract for outside personnel to perform inspections of ambulatory surgical centers as necessary. The department, when feasible, shall contract with a nonprofit, professional organizations that is approved as an accreditation agency, as defined in subdivision (d) of Section 1248, and has demonstrated the ability to administer the provisions of this chapter.
- (e) The department may make inspections and investigations as it deems necessary, to investigate complaints, follow up on adverse survey findings, or conduct periodic validation surveys.
- (f) An ambulatory surgical center that is licensed as a clinic pursuant to this section shall meet all of the following requirements:
- (1) The governing authority shall consist of one or more persons responsible for the organization and administration of the ambulatory surgical center. The governing authority shall do all of the following:

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(A) Adopt policies and procedures for the operation of the ambulatory surgical center to ensure compliance with state laws, regulations, and local ordinances.

- (B) Adopt the medical staff by laws.
- (C) Grant or deny clinical privileges of physicians and surgeons and other members of the medical staff and delineate, in writing, the clinical privileges of each medical staff member.
  - (D) Adopt a quality management plan.
- (E) Appoint an administrator who shall have authority and responsibility to manage the center.
- (2) The administrator shall be responsible to the governing authority and act as a liaison between the governing authority, medical staff, and facility staff. In addition, the administrator shall be responsible for all of the following:
- (A) Developing and implementing written administrative policies and procedures governing all of the following:
- (i) Personnel employment, orientation, in-service, staffing, and recordkeeping.
- (ii) Patient admissions, rights and responsibilities, grievances, medical treatment, and recordkeeping.
- (iii) Advance directives, a term which means a living will, prehospital medical care directive, or health care power of attorney.
  - (iv) Medications procurement and dispensing.
- (v) Contract services.
  - (vi) Infection control, housekeeping, and maintenance.
- (vii) Quality management and recordkeeping.
- 28 (viii) Emergency treatment and disaster plan.
- 29 (ix) Equipment inspection.
- 30 (B) Ensuring that all the policies and procedures are available to all employees in the facility.
  - (C) Developing and implementing a quality management plan. The purpose of the quality management plan is to monitor and evaluate the provision of all aspects of patient care, including physicians and surgeons and contracted services. The quality management plan shall be in writing and describe the objectives, organization, scope, and process for improving quality of care, which shall include the monitoring activities.
- 39 (D) Employing personnel to provide outpatient surgical 40 services. "Outpatient surgical services" means those anesthesia

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and surgical services provided to a patient in an ambulatory surgical center that do not require planned inpatient care following a surgical procedure.

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- (E) Ensuring that a pharmacy maintained by the center shall be registered as required by law.
- (F) Ensuring that pathology services are provided by a laboratory licensed, or exempt from licensure, as required by law.
- (G) Designating, in writing, an individual to be on duty, be in charge, and have access to all areas related to patient care and operation of the physical plant when the administrator is not present.
- (H) Posting a list of patient rights in a conspicuous area and making a reasonable effort to ensure that personnel apprise each patient or patient's representative of those rights and making a reasonable effort to ensure that language barriers or physical handicaps do not prevent each patient or patient's representative from becoming aware of those rights. "Patient's representative" means either a person acting on behalf of the patient with written consent of the patient or the patient's parent, legal guardian, or surrogate.
- (I) Ensuring that personnel are employed to meet the needs of patients and that job descriptions that define qualifications, duties, and responsibilities are established for all personnel.
- (J) Requiring personnel, prior to being employed and annually thereafter, to submit either one of the following as evidence of freedom from pulmonary tuberculosis:
- (i) A report of a negative Mantoux skin test taken within six months of submitting the report.
- (ii) A written statement from a physician stating that, upon an evaluation of a positive Mantoux skin test taken within six months of submitting the physician's statement or a history of a positive Mantoux skin test, the individual was found to be free from tuberculosis.
- (K) Providing orientation to each employee within the first week of employment. Orientation shall be specific to the position held by the employee.
- (L) Employing a registered nurse as the director of nursing who shall be responsible for the management and supervision of nursing services, including all of the following:

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(i) Developing and implementing written nursing and patient care policies and procedures, including medications administration, storage, and disposal.

- (ii) Ensuring that the facility is staffed based on the number of patients and their health care needs.
  - (iii) Participating in quality management activities.
- (iv) Appointing a registered nurse, in writing, to act in the absence of the director of nursing.
- (M) Maintaining a record of quality management activities and ensuring that any conclusions and recommendations on findings of quality management activities are reported to the governing authority.
- (N) Ensuring there is a current listing of all surgical procedures offered by the center and maintaining a chronological register of all surgical procedures performed.
- (O) Ensuring that a roster of medical staff that have surgical or anesthesia privileges at the center is available to the center staff, specifying the privileges and limitations of each person on the roster.
- (P) Ensuring that a medical record is established and maintained for each patient. Medical and facility staff shall sign with surnames and date their entries in a patient's medical record. Staff shall release medical record information only after receiving the patient's or patient representative's written consent, or as otherwise required or permitted by law. The medical record shall contain all of the following:
  - (i) Name and address of patient and patient's representative.
- (ii) Documentation of advance directives.
- 29 (iii) Admitting diagnosis.
  - (iv) Medical history and physical examination.
- 31 (v) Laboratory and radiology reports.
- 32 (vi) Consent forms.
- 33 (vii) Physician orders and notations.
- 34 (viii) Surgeon's operative report.
- 35 (ix) Anesthesia report.
- 36 (x) Nursing care notations.
- 37 (xi) Medications and treatments administered.
- 38 (xii) Written acknowledgment of receipt of discharge
- 39 instructions by the patient or patient's representative.

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(Q) Ensuring that the medical record of discharged patient is completed within 30 days of the discharge.

- (R) Ensuring that the medical records are maintained for a period of seven years. Medical records shall be retained onsite at the center, or retrievable by center staff within two hours of a request, for a period of one year from a patient's discharge.
- (S) Ensuring that written infection control policies and procedures are established and implemented for the surveillance, control, and prevention of infection. The policies and procedures shall include all of the following:
  - (i) Sterilization methods.

- (ii) Storage, maintenance, and distribution of sterile supplies and equipment.
  - (iii) Disposal of waste, including blood, body tissue, and fluid.
- (T) Ensuring that housekeeping and maintenance services are provided to maintain a safe and sanitary environment.
- (U) Ensuring that equipment is operational, inspected, and maintained in accordance with the center's policies and procedures. These policies and procedures shall address all of the following:
- (i) Testing, calibrating, servicing, or repairing of equipment to ensure that the equipment is free from fire and electrical hazards.
- (ii) Maintaining records documenting service and calibration information.
- (iii) The use, maintenance, and storage of oxygen and other flammable gases in accordance with applicable law.
- (iv) The use and maintenance of electrical equipment in accordance with applicable law.
- (V) Ensuring that employees who provide direct patient care shall:
  - (i) Be 18 years of age or older.
- (ii) Be certified in cardiopulmonary resuscitation within the first month of employment, and maintain current certification thereafter.
- (iii) Attend six hours of in-service education per year, which is exclusive of orientation, and cardiopulmonary resuscitation and which relates to the purposes and function of an ambulatory surgical center.
- (W) Ensuring that personnel records are maintained, including the application for employment, verification of training,

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certification, or licensure, initial proof of freedom from tuberculosis and annual verification statement thereafter, and orientation and in-service training records.

- (X) Ensuring the development of a written disaster plan of operation with procedures to be followed in the event of a fire or threat to patient safety and shall ensure that an emergency evacuation route is posted in every room where patients may be present, except restrooms.
- (Y) Ensuring all of the following with respect to emergency preparation:
- (i) Fire drills are conducted every three months, and all staff members on duty participate.
- (ii) Records of the drills include the date, time, and critique of the drills.
  - (iii) Records of the drills are maintained for one year.
- (3) A registered nurse shall function as a circulating nurse during each surgical procedure. A registered nurse shall be present in the recovery room whenever patients are in the recovery room. A registered nurse shall be in the facility until all patients are discharged. A registered nurse shall ensure that the patient or patient's representative acknowledges, in writing, the physician's written discharge instructions.
- (4) The individual responsible for performing the operative procedure shall complete an operative report and any necessary discharge instructions according to medical staff bylaws and ambulatory surgical center policies and procedures. The individual responsible for the administration of anesthesia shall complete an anesthesia report and any necessary discharge instructions according to medical staff bylaws and center policies and procedures.
- (5) A licensed physician and surgeon or licensed health care professional shall remain on the premises until all patients are discharged from the recovery room pursuant to subdivision (b) of Section 1248.15.
- (6) If an ambulatory surgical center ceases operation, the governing authority shall ensure the preservation of records and notify the department, in writing, of the location of the records.
- 38 (7) The medical staff shall have responsibility for all of the 39 following:

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(A) Approval of bylaws for the conduct of medical staff activities.

- (B) Conducting medical peer review and submitting recommendations to the governing authority for approval.
- (C) Establishing written policies and procedures that define the extent of emergency treatment to be performed in the center, including cardiopulmonary resuscitation procedures and provisions for the emergency transfer of a patient.
- (8) A medical staff physician shall admit patients to the facility who do not require overnight hospitalization or who do not pose a significant safety risk according to classifications determined by the American Society of Anesthesiologists and, beginning at a time of postoperative care, remain less than 24 hours and who do not, on average, require more than four hours of total operating time.
- (9) Within 30 days prior to admission, a medical staff member shall complete a medical history and physical examination of the patient. The individual responsible for performing the operative procedure shall document the preoperative diagnosis and the procedure to be performed. The nursing staff shall ensure that all of the following documents are in the patient's medical record prior to surgery:
- (A) A medical history and results of a current physical examination.
- (B) A preoperative diagnosis and the results of any laboratory tests or procedures relative to the surgery and the condition of the patient.
- (C) Validation of informed consent by the patient or patient's representative for the surgical procedure and care of the patient.
  - (D) Physicians orders.

- (10) Staff shall provide emergency treatment according to the center's policies and procedures.
- (11) The ambulatory surgical center shall pass an initial inspection for fire safety by the fire authority having jurisdiction.
- (12) The ambulatory surgical center shall ensure that there shall be two recovery beds for each operating room, for up to four operating rooms, whenever general anesthesia is administered. One additional recovery bed shall be required for each additional operating room.

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(13) Recovery beds or gurneys shall be located in a space that provides for a minimum of 70 square feet per bed, allowing three feet or more between beds and between the sides of a bed and the wall.

- (14) The ambulatory surgical center may provide recliner chairs in the recovery room area for patients who have not received general anesthesia.
- (15) The surgical center shall ensure that the following shall be available in the surgical suite:
  - (A) Oxygen and the means of administration.
- (B) Mechanical ventilatory assistance equipment, including 11 12 airways.
  - (C) Manual breathing bag, and suction apparatus.
  - (D) Cardiac monitor, defibrillator, and cardiopulmonary resuscitation drugs as determined by the facility's policies and procedures.
- 17 (E) Noninvasive blood pressure monitor.
  - (F) Oxygen saturation monitor.
  - (G) Temperature monitor.
- 20 (H) End-tidal CO<sub>2</sub>.
- SEC. 7. Section 1206 of the Health and Safety Code is 22 amended to read:
  - 1206. This chapter does not apply to the following:
  - (a) Except with respect to the option provided with regard to surgical clinics in paragraph (1) of subdivision (b) of Section 1204 and, further, with respect to specialty clinics specified in paragraph (2) (1) of subdivision (b) of Section 1204, any place or establishment owned or leased and operated as a clinic or office by one or more licensed health care practitioners and used as an office for the practice of their profession, within the scope of their license, regardless of the name used publicly to identify the place or establishment.
  - (b) Any clinic directly conducted, maintained, or operated by the United States or by any of its departments, officers, or agencies, and any primary care clinic specified in subdivision (a) of Section 1204 that is directly conducted, maintained, or operated by this state or by any of its political subdivisions or districts, or by any city. Nothing in this subdivision precludes the state department from adopting regulations that utilize clinic licensing standards as eligibility criteria for participation in

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programs funded wholly or partially under Title XVIII or XIX ofthe federal Social Security Act.

- (c) Any clinic conducted, maintained, or operated by a federally recognized Indian tribe or tribal organization, as defined in Section 450 or 1601 of Title 25 of the United States Code, that is located on land recognized as tribal land by the federal government.
- (d) Clinics conducted, operated, or maintained as outpatient departments of hospitals.
- (e) Any facility licensed as a health facility under Chapter 2 (commencing with Section 1250).
- (f) Any freestanding clinical or pathological laboratory licensed under Chapter 3 (commencing with Section 1200) of Division 2 of the Business and Professions Code.
- (g) A clinic operated by, or affiliated with, any institution of learning that teaches a recognized healing art and is approved by the state board or commission vested with responsibility for regulation of the practice of that healing art.
- (h) A clinic that is operated by a primary care community or free clinic and that is operated on separate premises from the licensed clinic and is only open for limited services of no more than 20 hours a week. An intermittent clinic as described in this subdivision shall, however, meet all other requirements of law, including administrative regulations and requirements, pertaining to fire and life safety.
- (i) The offices of physicians in group practice who provide a preponderance of their services to members of a comprehensive group practice prepayment health care service plan subject to Chapter 2.2 (commencing with Section 1340).
- (j) Student health centers operated by public institutions of higher education.
- (k) Nonprofit speech and hearing centers, as defined in Section 1201.5. Any nonprofit speech and hearing clinic desiring an exemption under this subdivision shall make application therefor to the director, who shall grant the exemption to any facility meeting the criteria of Section 1201.5. Notwithstanding the licensure exemption contained in this subdivision, a nonprofit speech and hearing center shall be deemed to be an organized outpatient clinic for purposes of qualifying for reimbursement as a rehabilitation center under the Medi-Cal Act (Chapter 7

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1 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code).

- (1) A clinic operated by a nonprofit corporation exempt from federal income taxation under paragraph (3) of subsection (c) of Section 501 of the Internal Revenue Code of 1954, as amended, or a statutory successor thereof, that conducts medical research and health education and provides health care to its patients through a group of 40 or more physicians and surgeons, who are independent contractors representing not less than 10 board-certified specialties, and not less than two-thirds of whom practice on a full-time basis at the clinic.
- (m) Any clinic, limited to in vivo diagnostic services by magnetic resonance imaging functions or radiological services under the direct and immediate supervision of a physician and surgeon who is licensed to practice in California. This shall not be construed to permit cardiac catheterization or any treatment modality in these clinics.
- (n) A clinic operated by an employer or jointly by two or more employers for their employees only, or by a group of employees, or jointly by employees and employers, without profit to the operators thereof or to any other person, for the prevention and treatment of accidental injuries to, and the care of the health of, the employees comprising the group.
- (o) A community mental health center, as defined in Section 5601.5 of the Welfare and Institutions Code.
- (p) (1) A clinic operated by a nonprofit corporation exempt from federal income taxation under paragraph (3) of subsection (c) of Section 501 of the Internal Revenue Code of 1954, as amended, or a statutory successor thereof, as an entity organized and operated exclusively for scientific and charitable purposes and that satisfied all of the following requirements on or before January 1, 2005:
- (A) Commenced conducting medical research on or before January 1, 1982, and continues to conduct medical research.
- (B) Conducted research in, among other areas, prostatic cancer, cardiovascular disease, electronic neural prosthetic devices, biological effects and medical uses of lasers, and human magnetic resonance imaging and spectroscopy.
- (C) Sponsored publication of at least 200 medical research articles in peer-reviewed publications.

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1 (D) Received grants and contracts from the National Institutes 2 of Health.

- (E) Held and licensed patents on medical technology.
- (F) Received charitable contributions and bequests totaling at least five million dollars (\$5,000,000).
  - (G) Provides health care services to patients only:

- (i) In conjunction with research being conducted on procedures or applications not approved or only partially approved for payment (I) under the Medicare program pursuant to Section 1359y(a)(1)(A) of Title 42 of the United States Code, or (II) by a health care service plan registered under Chapter 2.2 (commencing with Section 1340), or a disability insurer regulated under Chapter 1 (commencing with Section 10110) of Part 2 of Division 2 of the Insurance Code; provided that services may be provided by the clinic for an additional period of up to three years following the approvals, but only to the extent necessary to maintain clinical expertise in the procedure or application for purposes of actively providing training in the procedure or application for physicians and surgeons unrelated to the clinic.
- (ii) Through physicians and surgeons who, in the aggregate, devote no more than 30 percent of their professional time for the entity operating the clinic, on an annual basis, to direct patient care activities for which charges for professional services are paid.
- (H) Makes available to the public the general results of its research activities on at least an annual basis, subject to good faith protection of proprietary rights in its intellectual property.
- (I) Is a freestanding clinic, whose operations under this subdivision are not conducted in conjunction with any affiliated or associated health clinic or facility defined under this division, except a clinic exempt from licensure under subdivision (m). For purposes of this subparagraph, a freestanding clinic is defined as "affiliated" only if it directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, a clinic or health facility defined under this division, except a clinic exempt from licensure under subdivision (m). For purposes of this subparagraph, a freestanding clinic is defined as "associated" only if more than 20 percent of the directors or trustees of the clinic are also the directors or trustees

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of any individual clinic or health facility defined under this division, except a clinic exempt from licensure under subdivision (m). Any activity by a clinic under this subdivision in connection with an affiliated or associated entity shall fully comply with the requirements of this subdivision. This subparagraph shall not apply to agreements between a clinic and any entity for purposes of coordinating medical research.

- (2) By January 1, 2007, and every five years thereafter, the Legislature shall receive a report from each clinic meeting the criteria of this subdivision and any other interested party concerning the operation of the clinic's activities. The report shall include, but not be limited to, an evaluation of how the clinic impacted competition in the relevant health care market, and a detailed description of the clinic's research results and the level of acceptance by the payer community of the procedures performed at the clinic. The report shall also include a description of procedures performed both in clinics governed by this subdivision and those performed in other settings. The cost of preparing the reports shall be borne by the clinics that are required to submit them to the Legislature pursuant to this paragraph.
- SEC. 8. Section 1214.1 of the Health and Safety Code is amended to read:
- 1214.1. Notwithstanding the provisions of Section 1214, each application for a surgical clinic or a chronic dialysis clinic under this chapter for an initial license, renewal license, license upon change of ownership, or special permit shall be accompanied by an annual fee of three hundred dollars (\$300) plus an amount equal to 0.0003 times the clinic's operating cost for the last completed fiscal year.
- 31 SEC. 9. Section 1233 of the Health and Safety Code is 32 repealed.
  - 1233. A surgical clinic may restrict use of its facilities to members of the medical staff of the surgical clinic and other physicians and surgeons approved by the medical staff to practice at the clinic.
- 37 SEC. 10. Section 1242 of the Health and Safety Code is 38 amended to read:
- 39 1242. The director may temporarily suspend any license 40 issued to a specialty clinic or special permit prior to any hearing,

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when in his opinion such action is necessary to protect the public welfare. The director shall notify the licensee or holder of a special permit of the temporary suspension and the effective date thereof, and at the same time shall serve such provider with an accusation. Upon receipt of a notice of defense by the licensee or holder of a special permit, the director shall set the matter for hearing within 30 days after receipt of such notice. The temporary suspension shall remain in effect until-such the time-as when the hearing is completed and the director has made a final determination on the merits; provided, however, that the temporary suspension shall be deemed vacated if the director fails to make a final determination on the merits within 60 days after the original hearing has been completed. 

If the provisions of this chapter or the rules or regulations promulgated by the director are violated by a licensed-surgical elinic or chronic dialysis clinic or holder of a special permit which is a group, corporation, or other association, the director may suspend the license or special permit of—such the organization or may suspend the license or special permit as to any individual person within—such the organization who is responsible for-such the violation.

- SEC. 11. Section 1248.1 of the Health and Safety Code is amended to read:
- 1248.1. No association, corporation, firm, partnership, or person shall operate, manage, conduct, or maintain an outpatient setting in this state, unless the setting is one of the following:
- (a) An ambulatory surgical center that is certified to participate in the Medicare program under Title XVIII (42 U.S.C. Sec. 1395 et seq.) of the federal Social Security Act.
- (b) Any clinic conducted, maintained, or operated by a federally recognized Indian tribe or tribal organization, as defined in Section 450 or 1601 of Title 25 of the United States Code, and located on land recognized as tribal land by the federal government.
- (c) Any clinic directly conducted, maintained, or operated by the United States or by any of its departments, officers, or agencies.
  - (d) Any primary care clinic licensed under subdivision (a) and any surgical clinic licensed under subdivision (b) of Section 1204.

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(e) Any health facility licensed as a general acute care hospital under Chapter 2 (commencing with Section 1250).

- (f) Any outpatient setting to the extent that it is used by a dentist or physician and surgeon in compliance with Article 2.7 (commencing with Section 1646) or Article 2.8 (commencing with Section 1647) of Chapter 4 of Division 2 of the Business and Professions Code.
- (g) An outpatient setting accredited by an accreditation agency approved by the division pursuant to this chapter.
- (h) A setting, including, but not limited to, a mobile van, in which equipment is used to treat patients admitted to a facility described in subdivision (a), (d), or (e), and in which the procedures performed are staffed by the medical staff of, or other healthcare practitioners with clinical privileges at, the facility and are subject to the peer review process of the facility but which setting is not a part of a facility described in subdivision (a), (d), or (e).

Nothing in this section shall relieve an association, corporation, firm, partnership, or person from complying with all other provisions of law that are otherwise applicable.

SEC. 12. No reimbursement is required by this act pursuant to Section 6 of Article XIIIB of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIIIB of the California Constitution.